



COURAGE Chronicle

December 2000



MAKE PLANS NOW TO ATTEND THE SECOND ANNUAL COURAGE MEETING!



On February 12th through 14th, the second annual COURAGE investigators meeting will be held at the TradeWinds Resort Hotel on St. Petersburg Beach, Florida. The resort is located 35 minutes from the Tampa International Airport and offers a casual ambience, four pools, five tennis courts, fitness center, aerobics, sauna, children's center with supervised activities, nine restaurants and lounges with live entertainment, plus miles of white sandy beach.



Of course we're going to St. Petersburg to exchange information and find ways to make the COURAGE Trial even more successful than it has been so far. On Tuesday morning, Trial Leadership will present a progress report, highlighting recent changes in the Protocol as exemplified by the Amendments and Operations Memos released over the last year. Coordinators who were not at the last annual meeting in San Diego will be asked to attend a Monday afternoon session. Many issues involving the forms, core labs, Pentablot, data submission and reimbursement will be reviewed. The sessions held Tuesday afternoon and Wednesday will cover topics that have become increasingly important as the Trial moves through its second year, such as improving patient satisfaction with the trial and collecting/sending in data.

An Interview with Bob O'Rourke on turning 100

Q: Why have you been able to randomize such a large number of patients?

A: First, I sincerely believe in the COURAGE Trial and I have been able to communicate this to patients, even when they have been referred by another physician for PCI. I routinely review nearly all ECG exercise studies, myocardial perfusion studies and stress echocardiograms at the end of each day to assist my Coordinators in locating potential COURAGE patients.



Q: Do you not meet resistance from interventionalists when a patient with severe three-vessel CAD is randomized to aggressive medical therapy alone?

A: Initially this was the case. However, once several patients with severe multi-vessel disease improved on aggressive medical therapy alone, most of the interventionalists were more confident in allowing patients to be randomized to this arm. In fact, several interventionists who were previously skeptical now actively recruit appropriate patients into the Trial. The data so far indicate that we can successfully treat angina and coronary risk factors with medical therapy alone in almost every patient. Only one of our patients has thus far crossed over to the PCI arm. Most patients claim that they feel better now than they have in years and they appreciate the well-organized medical care and counseling. Our research unit receives several inquiries per day from patients wanting to be in the COURAGE Trial, often because they have observed the enthusiasm of the patients already enrolled in the Trial. As the number of successes increase enrollment becomes much easier.



DATA REMISSION & PAYMENTS

The COURAGE Trial is not only concerned with providing its patients with the best medical care and interventional therapy available, but it is also concerned with evaluating what therapies are optimal for what kind of patients. To accomplish this later set of goals, we must ensure that all the data are collected in a timely fashion and are remitted to West Haven and the Core Labs right away.

Payments for randomization currently range from \$1,000 to \$2,000 depending on the risk classification of the patient (see **Operations Memo No. 29**). Sites will be paid quarterly for those patients for whom **the following data forms and samples** have been sent to West Haven and the Angiographic Core Lab. These include: **Forms No. 2, 2A, 4, 8, & 9**, as well as **Form 10** (if treatment arm is PCI plus Meds), **Forms 6 & 7** if indicated by Form 2 for documentation of ischemia, **Form 11** if Form 4 indicates the patient was randomized while in the hospital, along with **Form 12 and/or 10** if the patient had an inpatient Cardio/Cerebro test and/or an inpatient PCI.

Send **Cine or CD and the 15 cm Catheter Tip** along with Form 2A to the Angiographic Core Lab, and the **ECG (appropriately labeled)** to West Haven.



PATIENT RANDOMIZATION UPDATE

		To Date	Since Annual Meeting
671	Audie L. Murphy VAMC— San Antonio	100	65
202	London Health Sciences Centres	72	55
È WEEK 77: TARGET ENROLLMENT per SITE: 44 26			
203	Montreal Heart Institute	42	30
580	Houston VA Medical Center	42	22
558	Durham VA Medical Center	34	15
506	Ann Arbor VA Medical Center	34	12
205	Queen Elizabeth II HSC	32	25
209	Sunnybrook & Women's College HSC	29	23
598	John C. McClellan VA – Little Rock	29	19
630	New York VA Medical Center	26	22
306	Mayo Clinic—Rochester	26	18
200	Foothills Hospital	25	19
663	Seattle VA Medical Center	24	15
501	Albuquerque VA Medical Center	23	16
312	University of Michigan Medical Center	22	17
596	Lexington VA Medical Center	22	14
304	Emory University Hospital	19	12
308	Mid America Heart Institute/Shawnee Mission	18	6
313	University of Oklahoma	17	11
212	Vancouver Hospital & Health Science Centre	16	16
584	Iowa City VAMC/Univ. of Iowa Hospital	16	12
210	The Toronto Hospital	16	9
207	St. Paul's Hospital	15	13
204	St. Michael's Hospital	14	14
626	Nashville VA Medical Center	13	9
201	Hamilton General Hospital, McMaster Clinic	12	9
301	Boston Medical Center	11	9
648	Portland VA Medical Center	10	10
208	Sudbury Memorial Hospital	10	9
211	University of Alberta Hospital	9	6
314	MIMA Century Research Associates	8	8
316	Hartford Hospital	7	7
315	Southern CA Kaiser Permanente Medical Gr.	5	5
626	Vanderbilt University Medical Center	4	4
***	All Terminated Sites	21	7
Total Patients as of 12/15/2000: -		823	

Notes from West Haven

- ♦ *If you haven't already done so, please send in all Informed Consent forms for the patients you have randomized, with their randomization number written on the upper right hand corner of the first page.*
- ♦ *Blacken the names on all ECGs that you send to West Haven.*



Calling All COURAGEOUS Chefs

Do you or your patients have any heart-friendly recipes that you would like to share? Send your recipes to be included in a COURAGE cookbook that will be provided to study patients. Fax to: 888-803-7439, or send to Liz at West Haven.